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INSURANCE AND REAL ESTATE COMMITTEE

Legislative Office Bldg.
Rm 2800
Hartford, CT 06106

AN ACT CONCERNING OFF-LABEL PRESCRIPTION DRUGS

Oral Testimony for SB 418. March 3rd, 2015

I would like to express my appreciation to Senator Joseph Crisco, Representative Robert W. Megna, Senator Kevin Kelly, Representative Robert Sampson and distinguished members of the Insurance and Real Estate Committee for allowing me to present oral testimony on behalf of Senate Bill 418, An Act Concerning Off-Label Prescription Drugs.

My name is Dr. Joseph B. Guarnaccia. I am the director of the Multiple Sclerosis Treatment Center at Griffin Hospital in Derby, CT.

I am here today because a number of my patients with multiple sclerosis have suffered unnecessarily because of inadequacies in the state's law governing off-label use of prescription medications. Multiple Sclerosis is a chronic disease of the central nervous system, which is often disabling if not treated early and, at times, aggressively. The disease carries significant personal and societal costs both direct and indirect, in terms of lost income from unemployment or under employment, expensive medical treatments, hospitalizations, reduced quality of life and the economic and personal burden on caregivers.

Off-label use of FDA-approved medications are necessary to slow or prevent disease progression and to ease symptoms of multiple sclerosis as well as other medical conditions, including cancer.

In fact, as much as 50% of drug prescribing is off label.

Connecticut statutes do cover off-label medication prescribing. However, the existing statutes only require healthcare insurers to cover off-label medications if that use is cited in one of three medical reference compendia. Two of these compendia are no longer in print (1).

Therefore, existing state law relies on two obsolete references.

SB 418 seeks to remedy that situation by adding off-label uses for medication if there is evidence cited from studies in "peer reviewed medical literature," which is defined in the bill.

It should be made very clear that off-label prescribing is not improper prescribing and heavily relies on evidence-based medicine. Off-label prescribing reflects norms of community and academically based medical practice, based on expanding medical knowledge, either through clinical or laboratory discoveries of new uses for older drugs. It is often recognized that diverse diseases may have similar genetic or other underlying causes and, therefore, it is natural to test drugs for off-label indications.

The FDA does not prohibit or otherwise regulate the use of approved medications off-label. It recognizes that pharmaceutical companies may have little motivation to seek additional FDA-approved indications for a variety of reasons, including limited profitability, expiration of patent protection, costs of conducting rigorous clinical trials and the FDA's own lengthy review process.

At the same time, there is a societal benefit in that off-label prescribing "speeds medical innovations to patients, increases the number of drugs available to doctors, and lowers the costs of medical innovation. Because of these benefits, off-label prescribing is common in the United States today. The largely unregulated system of off-label prescribing is working well, and it should be extended," according to one comprehensive medical review article (2). Furthermore, off-label medications are often less costly than on-label medications (3).

Thirty-six states today, including Connecticut, have statutes that require healthcare insurers to cover off-label drug treatment.

Twenty-seven of those states allow coverage based on "peer reviewed medical literature" in addition to references in standard compendia.

Connecticut is among seven states which extend coverage of off-label prescribing to chronic or disabling conditions in addition to cancer. Of these, Connecticut is the only state which does not allow evidence from peer reviewed medical literature. SB 418 is designed to address that anomaly.

In closing, I'd like to respond to the potential argument, "since healthcare insurers already cover a number of off-label uses, why amend the law?"

In fact, physicians are facing more healthcare insurer restrictions in their ability to prescribe off-label or so-called non-formulary medications. Even older, relatively inexpensive generic drugs, are getting harder to prescribe because either of outright rejection by healthcare insurers with little recourse through a 'peer to peer' review process or an arduous preapproval process that takes up valuable physician and staff time and effort.

Thank you for your attention,

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Notes

1) The three compendia are: The U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional (USP DI); (2) The American Medical Association's Drug Evaluations (AMA DE); and, (3) The American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information (AHFS-DI). Only the AHFS-DI is up-to-date. The USP-DI was last published in 2005 and the AMA-DE last published in 1986.
2) Tabarrock, A. *The Independent Review, .V, n.1, Summer 2000, ISSN 1086-1653, Copyright © 2000, pp. 25–53*
3) Rituximab, for example, whose efficacy in multiple sclerosis is widely accepted by MS experts across the country (See, http://www.gopetition.com/petitions/support-of-insurance-coverage-of-rituximab-for-multiple-sclerosis.html), costs 50% or less than on-label MS treatments.
4) Source: National Cancer Institute, State Cancer Legislative Database Program, Bethesda, MD: SCLD

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February 24, 2015

Insurance and Real Estate Committee

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SUPPORT FOR SB 418. AN ACT CONCERNING OFF-LABEL PRESCRIPTION DRUGS

Dear Sen. Joseph Crisco and Rep. Robert W. Megna,

As a practitioner who treats multiple sclerosis and a member of the physician community of the state of Connecticut, I strongly endorse SB 418. SB 418 prevents health insurers from excluding coverage of prescription drugs on the basis that it is 'off-label' for the treatment of a particular medical condition if support for such treatment is found in "peer reviewed medical literature generally recognized by the relevant medical community." A prescription drug is deemed off-label when it is prescribed for a medical condition for which is it not specifically indicated by the FDA.

As the FDA specifically does not engage in the practice of medicine, it recognizes physician discretion in off-label drug prescribing:

"Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects." (FDA, 2015)

The current state law is obsolete because it supports an off-label use of a drug only if it is supported by one of three medical references:

(1) The U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional (USP DI);

(2) The American Medical Association's Drug Evaluations (AMA DE);

(3) The American Society of Hospital Health-System Pharmacists' American Hospital Formulary Service Drug Information (AHFS-DI).

Of the three compendia, only the AHFS-DI is still in print. The USP-DI was last published in 2005 and the AMA-DE last published in 1986.

The proposed new legislation expands the criteria to include "peer reviewed medical literature," which is defined in the bill.

Prescription drugs are frequently used off-label for a variety of medical conditions. As much as 50 percent of drug prescribing is off-label. Often these are older, generic drugs which are generally acknowledged by physicians as being effective in the treatment of a variety of medical conditions but have not been through the complex, expensive and time consuming studies that are required for FDA indication for a specific disease. While medications prescribed off-label may be as efficacious as on-label treatments, a pharmaceutical manufacturer may not pursue FDA approval for that condition because of a number of possible factors, e.g., limited profit potential, patent expiration, competition with a company's existing drug.

Off-label drugs are no more expensive than on label-label drugs and are usually tried when a patient's medical condition is not responsive to on label treatments.

The problem is that some healthcare insurers refuse to cover an off- label use of a medication by citing the three medical compendia or by determining the medication is "not medically necessary" in a somewhat Orwellian twist given the gravity of the patient's disease. When the mediations does not conform to the insurer's medical policy, we are told in sweeping fashion that the medication lacks sufficient evidence for effectiveness. However, often Medicare and the State's Medicaid programs do find sufficient evidence to use a particular medication off-label for the same condition.

Furthermore, different commercial health care insurers can have different medical policies for the same off-label use for a medication. This can be stated explicitly in their medical guidelines or the drug can be approved based on a 'peer-to-peer' discussion between the treating physician and the insurer's physician reviewer. While all healthcare insurers have a review process or an appeals process, some treat it as a formal exercise in de facto denials of the medication. Many times, the physician reviewer has no expertise in treating the disease in question.

The formal appeal process is time consuming, exhausting for the patient and the physician, and, as the Office of Healthcare Advocacy can attest, often futile. This has real consequences for a patient with a progressively disabling or terminal disease.

I believe that it is imperative that the State of Connecticut impose fairness and rationality to this process, as have nearly 20 other states with similar legislation. It is time for the State of Connecticut to recognize the wisdom of allowing physicians to treat their patients appropriately and the rights of patients to receive effective treatments.

This bill does not impose extra costs on healthcare insurers and is not a mandate for healthcare insurers to cover any specific medication or scientifically unsound treatment.

Sincerely,

Joseph B. Guarnaccia, MD

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